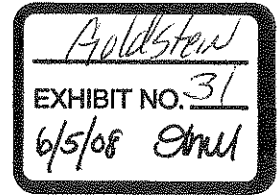


PAREXEL
MEDICAL MARKETING SERVICES



SEROQUEL BEST
Meeting Minutes
November 24, 2004

BEST – BIPOLAR EXECUTION & STRATEGY TEAM

Attendees:

AZ: Sophie Eynon (SE), John P. Gonzalez (JPG), Bill Hess (BH), Wayne Macfadden (WM), Karin Mueller (KM), Jamie Mullen (JM), Christine Ney (CN), Björn Paulsson (BP), Göran Stening (GS), John Tumas (JT), Celeste Williams-Hughes (CWH)

PAREXEL MMS: Lauren Duby (LD), Michelle O'Donovan (MO), Claudia Piano (CP), Bill Wolvey (BW)

Apologies:

Denise Campbell (DeC), Rohini Chitra (RC), Stephanie Daniels (SD), Jeff Goldstein (JG), Richard Olbrich (RO), Ed Repp (ER), Sue Souder (SS), Alison Wilkie (AW)

Copies to:

Carla Burigatto, Louise Marland, Tina Olsson, Jacquie Pesa, Kitty Rajagopalan

BOLDER/TRIAL 49 PUBLICATIONS UPDATE

- **M02:** WM filled BEST team in on issues pertaining to authorship of M02 manuscript. WM is confident he alleviated **REDACTED** and **REDACTED** concerns.

M04: **REDACTED** agreed to author and PXL MMS is setting up teleconference for **REDACTED** to speak to WM and JT week of December 6th.

T49 PUBLICATIONS ADVISORY BOARD TELECONFERENCE UPDATE

CP updated the team on the BOLDER Advisory Board Telecon #2 logistics:

Date/Time: December 6, 2004; 1pm - 3pm EST

Faculty: **REDACTED**

REDACTED

AstraZeneca: John Gonzalez, John Tumas, Wayne McFadden, Margaret Minkwitz, Ed Repp
Parexel MMS: Lauren Duby, Michelle O'Donovan, Aruna Seth

ACTION PXL MMS: send draft agenda to JG/JT for discussion

HYPOTHESES ACTION GROUP UPDATE

JG and PXL MMS re-capped HAG 11/22 telecon with **REDACTED** and **REDACTED**. The faculty did not push-back on any of the manuscript priorities, and gave helpful suggestions for authorship. They suggested the next 'live' HAG meeting with faculty should take place in June

at ICBD. The BEST team agreed this should be done in conjunction with an international Bipolar Advisory Board.

REVIEW OF NON-BOLDER MANUSCRIPTS/POSTER PRESENTATIONS

Not all of these were discussed in detail at the meeting

Mania:

The team reviewed the status of the primary publications:

- Trial 104: The team discussed BP's concern about including haloperidol data, as requested by journal reviewers.

ACTION PXL MMS: set up telecon with AZ team to discuss next steps

- Trial 104+105: The rejection and resubmission (including journal choices) of the Trial 104/105 manuscript were discussed. The team agreed that from a commercial perspective, the data must be published quickly in order to support key claims for the brand. Therefore, if the authors recommend anything that will slow up this process, AZ should consider asking them to step down from this project.

ACTION PXL MMS: Set up telecon with [REDACTED] and [REDACTED] to discuss journal comments and re-submission (include Alison and Björn in call). PXL MMS to research lower tier journals.

Other mania manuscript activity:

JG suggested the publication of the secondary mania manuscripts together as a supplement in the interest of getting them published expediently. Potential manuscripts already in progress that could be considered are:

- Safety and Tolerability of Quetiapine [REDACTED]
- Randomized Studies of Quetiapine in Bipolar Mania—Specificity of Effect Versus Placebo [REDACTED]
- Quetiapine for the Treatment of Agitation, Aggression, and Hostility in Mania Associated With Bipolar Disorder [REDACTED]
- Mania Remission Rates and Euthymia with Quetiapine Combination Therapy [REDACTED]
- Sustained Remission/Euthymia With Monotherapy for Bipolar Mania [REDACTED]
- Effective Dose of Quetiapine in the Treatment of Bipolar Mania [REDACTED]

The MCs have expressed the need for secondary mania data ASAP. JG pointed out that the HAG manuscripts will address the need for credible, peer-reviewed publications. The team agreed they would prefer this supplement be peer-reviewed and indexed in Medline, if possible.

ACTION PXL MMS: research journal options for supplement

CONGRESS ACTIVITY

[REDACTED]

REDACTED

REACH PROGRAM MANUSCRIPTS

These were not discussed at the meeting. There are several manuscripts in development to disseminate REACH program messages to different target audiences:

REDACTED

ISSs

These were not discussed at the meeting. The status of ongoing ISSs is as follows:

- Combination Quetiapine Therapy in Long-Term Treatment of Patients With Refractory Bipolar I Disorders (Italy) – REDACTED was rejected as a Brief Report from *J Clin Psychiatry*. Authors want to resubmit to *Bipolar Disorders*
ACTION PXL MMS: Assist authors in resubmission to *Bipolar Disorders*
- Safety and Tolerability of Rapid Quetiapine Dose Escalation in Patients With Bipolar Mania: An Open-Label Study (Malaysia) – REDACTED has been revised based on additional analyses requested. Comments received from author. Some AZ comments to be resolved
ACTION PXL MMS: Revise manuscript and assist author in submission to *Human Psychopharmacology*
- Quetiapine as Add-on Therapy in Psychotic Depression (Austria) – REDACTED Study data has been developed into a manuscript and reviewed by the AZ team. PXL MMS is revising this based on initial comments from the author
- Quetiapine Reduces Persistent Anxiety in Patients With Major Depressive Disorder (US) - REDACTED Study data were presented at ECNP
ACTION PXL MMS/SS: determine next steps regarding manuscript development

- Quetiapine in the Treatment of Agitation in Major Depressive Disorder (Germany) – REDACTED
Study data were presented at ECNP
- Quetiapine vs Divalproex for the Treatment of Hospitalized Patients With Bipolar Mania – REDACTED
REDACTED Poster presented at AACAP; abstract accepted at ACNP. PXL MMS assisting REDACTED
ED with manuscript draft

OTHER BUSINESS:

Acknowledgement of Editorial Assistance:

JPG explained the AZ policy regarding acknowledgement of editorial assistance from 3rd parties, eg, crediting individuals from medical communication agencies who have assisted with publications. There may be implications of this in the way we work.

ACTION PXL MMS: Conduct 'audit' of how this is being handled by other pharma companies and report back to BEST team

KOL compensation:

There was a discussion about financial compensation for all authors. It was agreed that discussion requires separate time, perhaps with commercial group.

ACTION BH: Bring up at next brand team meeting to ascertain next steps.

Request from REDACTED
REDACTED JPG re-capped request that came to REDACTED
REDACTED from MIS regarding a REDACTED who wants to use 104+105 monotherapy data at week 3 to compare to other products at week 3. KM asked for approval to release data to REDACTED JG asked BEST team for approval. BP and GS said they didn't think quetiapine would come out looking bad, and agreed it should be done. JM suggested GS and BP have telecon with REDACTED
REDACTED to discuss further his exact needs.

ACTION KM: set up telecon with GS, BP, and REDACTED

Request from REDACTED
REDACTED AW visited REDACTED (colleague of REDACTED at University of Pennsylvania. He has a large # of case studies re: rapid initiation of tx with quetiapine. He'd like to use these cases to write up a prospective publication. The BEST team agreed that while a 'soft' publication, this may support the faster onset of action message. JM and BP both expressed concern about deciding which of his patients to use without seeing his database first. JM proposed a telecon with himself, AW, and REDACTED to ascertain whether a homogenous cohort can be determined. REDACTED also wants to publish a paper combining pharmacological rationale with dosing in clinical practice. Team agreed this could be discussed on telecon.

ACTION AW: arrange telecon with REDACTED and JM